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| 09/981,676 | 10/16/2001 | Eija Marjut Pirhonen | 01942-00003 | 6631 |

7590 09/26/2006
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| EXAMINER |
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THOMPSON, CAMIE S

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| ART UNIT | PAPER NUMBER |
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1774

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,676

Applicant(s)

PIRHONEN, EIJA MARJUT

Examiner

Camie S. Thompson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on amendment filed 6/23/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-37 and 50-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-12,27,32,33,37 and 50-52 is/are allowed.
- 6) ☒ Claim(s) 1,3-5,13-26,29,30 and 34-36 is/are rejected.
- 7) ☒ Claim(s) 28, 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment and accompanying remarks filed June 23, 2006 are acknowledged.
2. Examiner acknowledges amended claims 1, 8, 13, 25, 27, 33 and 37.
3. Examiner acknowledges newly added claims 50-52.
4. The rejection of claim 13 under 35 U.S.C. 102(b) as being anticipated by Scheicher, U.S. Patent Number 4,278,630 is overcome by applicant's amendment.
5. The rejection of claims 6-7 and 11-12 under 35 U.S.C. 102(b) as being anticipated by WO86/04088 is withdrawn due to applicant's argument.
6. The rejection of claims 13-14 under 35 U.S.C. 102(b) as being anticipated by WO 98/47465 is withdrawn due to applicant's argument.
7. The rejection of claims 1, 3-6, 9-10, 15-26, 29-32 and 34-36 under 35 U.S.C. 103(a) as being unpatentable over WO 86/04088 is withdrawn due to applicant's argument.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1, 3-5, 13-14, 17-18, 21-26, 29-30 and 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Ylanen et al., U. S. Patent Number 6,517,857.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Ylanen discloses a porous product made from bioactive glass fibers wherein the product is an implant (see column 2, lines 33-68). The reference discloses the bioactive glasses as having a composition of SiO₂ 53-60% by weight; Na₂O 0-34% by weight; K₂O 1-20% by weight; MgO 0-5% by weight; CaO 5-25% by weight; B₂O₃ 0-4%; P₂O₅ 0.5-6% by weight (see column 3, lines 44-68). The reference discloses that the fibers can be in microsize (see column 4, lines 39-44). Additionally, column 4 of the reference discloses that promotes new bone growth. It is disclosed in column 4, lines 17-21 of the Ylanen reference that the shorter fibers form a mat. Reference 12 discloses that the product can be impregnated so as to be molded into a desired shape. The

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reference does not disclose that the fibers are sintered together. The sintering of the fibers is a process limitation and is not given any patentable weight. Additionally, the temperature at which the fibers are sintered are not given any patentable weight. The product of the reference is the same product as the product of the instant application. The reference uses bioactive fibers together to form an implant, as does the present claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 15-16, 19-20 and 29-30 are rejected under 35 U.S.C. 103(a) as being obvious over Ylanen et al., 6,517,857.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in

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the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2). Ylanen discloses a porous product made from bioactive glass fibers wherein the product is an implant (see column 2, lines 33-68). The reference discloses the bioactive glasses as having a composition of SiO₂ 53-60% by weight; Na₂O 0-34% by weight; K₂O 1-20% by weight; MgO 0-5% by weight; CaO 5-25% by weight; B₂O₃ 0-4%; P₂O₅ 0.5-6% by weight (see column 3, lines 44-68). The reference discloses that the fibers can be in microsize (see column 4, lines 39-44). Additionally, column 4 of the reference disclose that promotes new bone growth. It is disclosed in column 4, lines 17-21 of the Ylanen reference that the shorter fibers form a mat. Reference 12 discloses that the product can be impregnated so as to be molded into a desired shape. The reference does not disclose the length or diameter of the fibers. However, the reference does disclose in column 4, lines 14-16 that the length of the fibers varies. Therefore, it would have been obvious to one of ordinary skill in the art to have the fibers have a length from about 2 mm to about 30 mm; a diameter of about 0.010-1.0 mm in order to have a porous product that can be manufactured into a mat (see column 4, lines 14-22).

12. Claims 28^{and} 31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not provide for the recited sintered glass scaffold

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further including the scaffold is attached to a biocompatible polymeric film and is a carrier for a bone morphogenetic protein

13. Claims 6-12, 27, 32-33, 37 and 50-52 are allowed. The prior art does not provide for a sintered glass scaffold comprising glass fibers sintered together to form the scaffold, wherein the fibers have a coating of one or more biocompatible polymers or copolymers, wherein the biocompatible polymer is selected from the group consisting of polyglycolide, polylactide, poly- β -hydroxybutyric acid, polydioxanone, polyvinylalcohol, polyesteramine, their copolymers and polymer blends.

Response to Arguments


14. Applicant's arguments with respect to the instant claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Camie S. Thompson whose telephone number is (571) 272-1530. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena L Dye, can be reached at (571) 272-3186. The fax phone number for the Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RENA DYE
SUPERVISORY PATENT EXAMINER
A.U. 1774 9/18/04